



AUG 22 2002

GE Medical Systems

Page 1 of 2

General Electric Company
P.O. Box 414, Milwaukee, WI 53201

510(k) Summary

K022397

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.92(c).

Submitter: GE Medical Systems
PO Box 414
Milwaukee, WI 53201

Contact Person: Larry A. Kroger Ph.D.
Manager, Regulatory Programs

Telephone: 262- 544-3894

Fax: 262- 544-3863

Date Prepared: July 16, 2002

Device Name:

Signa[®] 3.0T Magnetic Resonance System
Magnetic Resonance Diagnostic System, 21 CFR 892.1000, 90-LNH

Marketed Device:

The Signa[®] 3.0T Magnetic Resonance System is substantially equivalent to the currently marketed 3.0T Signa[®] VH/i transmit/Receive Body Imaging Coil (K003613) and the 3.0 T Signa[®] VH/i system (K990550).

Device Description:

The Signa[®] 3.0T magnetic resonance system is a diagnostic imaging device that produces transverse, coronal, sagittal and oblique images of the internal structures of the head, neck, spine, abdomen/thorax and the extremities. The Signa[®] 3.0T system is designed to support high resolution imaging and multinuclear spectroscopy. Previously cleared software options, coils, and other accessories may be used with the Signa[®] 3.0T MR System.

Indications for Use:

The indications for use for the 3.0T Signa[®]VH/i (Signa[®] 3.0T MR System) Transmit/Receive Body Imaging Coil expands the imaging capability of the 3.0T Signa[®]VH/i MR Imaging System.

The Transmit/Receive Body Imaging Coil is intended for imaging of the Neck, Spine, Abdomen/Thorax and the extremities.

Comparison with Predicate Device:

The Signa[®] 3.0T Magnetic Resonance System is a modification of the 3.0T Signa[®] VH/i MR system (K990550) by combining the 3.0T Signa[®] VH/i T/R Body Imaging Coil (K003613) with the 3.0T Signa[®] VH/i MR system (K990550). It has the same basic technological characteristics, and, uses the



same basic design, construction, and materials. It has the same intended use, and operating modes as the predicate device.

Summary of Studies:

Testing was performed to demonstrate that the design modifications to the Signa[®] 3.0T MR System meet predetermined acceptance criteria.

Conclusion:

The results of the testing described above demonstrate that the Signa[®] 3.0T MR System is substantially equivalent to the currently cleared 3.0T Signa[®] VH/i transmit/Receive Body Imaging Coil and the 3.0 T Signa[®] VH/i system magnetic resonance system.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 22 2002

Larry Kroger, Ph.D.
Regulatory Affairs Manager
GE Medical Systems
P.O. Box 414
MILWAUKEE WI 53201

Re: K022397
Trade/Device Name: GE Signa® 3.0T MR system
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance
diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: July 18, 2002
Received: July 23, 2002

Dear Dr. Kroger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

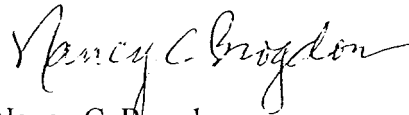
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K022397

Device Name: GE Signa[®] 3.0T Magnetic Resonance System

Indications For Use:

The indications for use for the 3.0T Signa[®]VH/i (Signa[®] 3.0T MR System) Transmit/Receive Body Imaging Coil expands the imaging capability of the 3.0T Signa[®]VH/i MR Imaging System.

The Transmit/Receive Body Imaging Coil is intended for imaging of the Neck, Spine, Abdomen/Thorax and the extremities.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR Over-The-Counter Use ☐

Nancy Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022397